REMARKS/ARGUMENTS

Claims 1-7 are pending herein. Claim 1 has been rewritten to clarify that the claimed semi-solid enteral nutrition product is enterally administered, not orally, but directly to a stomach or intestines of a dysphagic patient. Claim 1 has also been rewritten to recite that the claimed liquid nutrient solution component is one of a defined formula diet and a semi-digested diet. Applicant respectfully submits that support for rewritten claim 1 can be found, for example, in paragraphs [0003] and [0125] of the substitute specification filed on January 24, 2005, and that no new matter has been added.

1. Claims 1-7 were rejected under §103(a) over the combined disclosures of the Ying recipe for rice pudding, Carlsson (U.S. Patent No. 5,716,639) and the Kabushiki article. To the extent that the PTO might attempt to assert this rejection against rewritten claim 1, it is respectfully traversed.

Rewritten independent claim 1 recites a semi-solid enteral nutrition product for enteral administration, not orally, but directly to a stomach or intestines of a dysphagic patient. This limitation, although recited in the preamble, in fact distinguishes the claimed enteral nutrition product from other enteral nutrition products that are instead orally administered. The semi-solid enteral nutrition product is administered from an external container connected to an external portion of a feeding tube provided through a through-hole of a stoma formed through a portion of the abdominal and stomach walls of the patient upon the application of pressure to the external container. The semi-solid enteral nutrition product comprises a semi-solid material having a substantially self-supporting consistency that deforms to flow under an externally applied load without liquefying and that is capable of containing a higher concentration of a nutrient component than a liquid. The semi-solid material comprises a mixture of a liquid nutrient solution and a semi-solidifying agent comprising one of agar and a whole egg that is added to the liquid nutrient solution. The liquid nutrient solution is one of a defined formula diet and a semi-digested diet.

The mixture comprises the semi-solidifying agent and the liquid nutrient solution in a predetermined ratio sufficient to ensure that the self-supporting consistency of the semi-solid enteral nutrition product remains substantially unchanged before, during, and after enteral administration of the semi-solid enteral nutrition product into the patient, and the self-supporting consistency of the semi-solid enteral nutrition product is further maintained within the stomach or the intestines of the patient such that the semi-solid enteral nutrition product does not liquefy due to the body temperature of the patient, to thereby prevent the patient from experiencing gastro-esophageal reflux.

The PTO asserted that "the intended use of the composition is for enteral delivery" and that when "the preamble [is used] only to state a purpose or intended use for the invention the preamble is not a claim limitation" citing to *Rowe v Dror* (see Office Action, page 4, lines 16-19). At the same time, however, it has been well-established according to U.S patent law, that "where a patentee uses the claim preamble to recite structural limitations of the claimed invention, the PTO and courts must give effect to that usage." *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (CAFC 1997).

In the present case, the preamble of claim 1 does, in fact, recite positive and distinguishing structural claim limitations, as mentioned above, and is not merely a statement relating to an intended use. Claim 1 recites a semi-solid enteral nutrition product for enteral administration, not orally, but directly to a stomach or intestines. The recitation that the enteral nutrition product is for enteral administration is not an intended use, but a description of the exact nature of the semi-solid enteral nutrition product being claimed. Applicant respectfully submits that it is commonly understood, particularly among those skilled in the art of medical nutrition, that enteral nutrition is a way to provide specific medically formulated food usually through a tube placed at a location in the gastrointestinal tract (see On-line medical dictionary definitions attached in Appendix A hereto). An enteral nutrition product, therefore, is a specific medical nutrition product whose structure is intimately tied to its mode of delivery and operation. One skilled in the art would understand that an orally administered nutrition product is not the same, structurally speaking, as one

administered directly to other portions of the gastrointestinal system. The fact that the claimed enteral nutrition product is enterally administered, rather than orally administered, clearly and directly relates to the structural features of the claimed semi-solid enteral nutrition product, which are even further defined in conjunction with the other claim limitations recited in claim 1.

Applicant respectfully submits that the claimed semi-solid enteral nutrition product is just that, an enteral nutrition product for enteral, not oral, administration, and stating that fact further defines the structure and distinguishes the claimed product from orally consumable liquid or solid nutrition products, as well as other liquid type tube feeding nutrition products, for example. Rice pudding, on the other hand, simply is not an enteral nutrition product, medically speaking, regardless of the mode of administration. Applicant respectfully submits that claim 1 is narrowly tailored to cover a specific product, and is not open to the overly broad interpretation asserted by the PTO for the reasons explained above, for example, and for the additional reasons explained below.

The PTO asserted that it would have been obvious for a skilled artisan to have arrived at the claimed enteral nutrition product in view of a conventional dessert recipe (Ying), a patent relating to nutritional emulsions (Carlsson) that are not orally consumed, and an article about the delivery of enteral nutrition (Kabushiki).

By combining the rice pudding recipe with these otherwise completely unrelated references, the PTO asserted that it would have been obvious to use agar, as in Carlsson, to thicken the rice pudding dessert of Ying and to then administer the rice pudding enterally, rather than orally, directly into the stomach or intestines of a patient, using the device and method of Kabushiki. Applicant respectfully submits, however, that the PTO's assertions are incorrect for the reasons explained in the Amendment filed on May 11, 2006, the entirety of which is incorporated herein by reference, and for at least the additional reasons explained below.

As mentioned before, Ying's recipe already includes a suitable thickener, namely eggs, for the rice pudding dessert. Again, Applicant respectfully submits that

there is no evidence that agar, as taught in connection with the emulsions in Carlsson, would actually, or could even possibly provide better thickening behavior for rice pudding than that which is already accomplished by the eggs in the Ying recipe (in conjunction with the other ingredients). There is also no evidence that the otherwise typically sweet dessert would even be able to sustain its intended taste characteristics if the egg were replaced with agar.

In addition, as mentioned above, rice pudding is just not an enteral nutrition product, and there is no evidence that a rice pudding dessert could possibly be suitably used in conjunction with any enteral emulsions based on the teachings in Carlsson.

Even if, *arguendo*, one skilled in the culinary arts did, for some reason, choose to disregard any taste considerations and use agar in Ying's rice pudding, or even if they kept the eggs in Ying's rice pudding, Applicant respectfully submits that such skilled culinary artisans could not possibly have then assumed the role of a skilled medical nutrition practitioner so as to be motivated to enterally administer a culinary dessert product intended for oral consumption. To assert that any culinary artisan, or even a reasonable lay person, would do so is simply unreasonable.

Moreover, Applicant respectfully submits that one skilled in the medical nutrition arts would readily understand, from a medical standpoint, that while rice pudding may be a tasty dessert, rice pudding still is not an enteral nutrition product, and is not a defined formula diet or a semi-digested diet. Rice pudding, according to Ying, does not even contain the claimed liquid nutrient solution. Attached hereto in Appendix B are copies of technical references submitted to support Applicant's position that skilled medical professionals readily understand that the terms "enteral nutrition" and "defined formula diet," for example, relate to specific medically classified products. The established terms of art "enteral nutrition product" and "defined formula diet," therefore, serve to further distinguish the claimed enteral nutrition product, including a defined formula diet and/or semi-digested diet liquid nutrient solution, from other types of ordinarily orally consumed food products, like rice pudding.

Furthermore, Applicant respectfully submits that none of the applied references are directed to providing an enteral nutrition product to a dysphagic patient specifically to prevent that dysphagic patient from experiencing and suffering from gastro-esophageal reflux, as claimed. Further still, Applicant respectfully submits that none of the applied references disclose or even remotely suggest that there is, or even could be any particular relationship between an enteral nutrition product having the claimed self-sustaining consistency and the prevention of reduction of gastro-esophageal reflux. Indeed, such a relationship has remained unknown and unrecognized prior to the present invention. Absent the recognition of any such relationship, one skilled in the art could not possibly have been motivated to ever attempt to try to use a modified dessert custard, based on the fact that it is edible and has a semi-solid gelatinous consistency, for direct enteral administration to ill patients for life-sustaining nutritional purposes, much less to prevent gastro esophageal reflux in particular.

Applicant respectfully submits that the applied references, in any combination, fail to establish the importance of, or even recognize, any specific ratio between the amount of eggs and milk that would be required, or would even sufficient, to ensure the proper medical nutrition and provide and maintain the claimed self-supporting consistency under the claimed conditions (i.e., within the stomach or intestines of a patient irrespective of the body temperature). Indeed, Applicant respectfully submits that one skilled in the culinary arts would find that such heretofore unrecognized yet medically desirable consistency features would be completely irrelevant considerations for making a rice pudding dessert, or any culinary creation. Such culinary artisans would instead be concerned with providing the ordinarily desired textures and consistency associated with that of rice pudding, which are judged orally. Indeed, deliberately attempting to provide a dessert having such a thickened consistency so as to meet the claim limitations would be highly undesirable in that such a consistency could potentially interfere with enjoyable ingestion of the orally administered dessert for an ordinary person.

In addition to the above, Applicant respectfully submits that the claimed invention provides unexpected results, and unexpected benefits, in providing a semi-solid enteral nutrition product that effectively prevents the occurrence of gastro-esophageal reflux in dysphagic patients, as explained in the May 11, 2006 Amendment.

For at least the foregoing reasons, Applicant respectfully submits that all claims pending herein define patentable subject matter over the applied references, and respectfully requests that the above rejection be reconsidered and withdrawn.

If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

April 20, 2007
Date

Stephen P. Burr
Reg. No. 32,970

Nicole J. Buckner
Reg. No. 51,508

SPB/NB/gmh

Attachments:
Appendix A - supporting dictionary definitions
Appendix B - technical references

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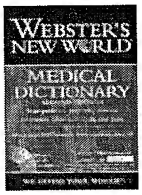

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Definition of Enteral nutrition

Enteral nutrition: A way to provide food through a tube placed in the nose, the stomach, or the small intestine A tube in the nose is called a nasogastric tube or nasoenteral tube A tube that goes through the skin into the stomach is called a gastrostomy or percutaneous endoscopic gastrostomy (PEG) A tube into the small intestine is called a jejunostomy or percutaneous endoscopic jejunostomy (PEJ) tube.

Enteral nutrition is often called tube feeding See also: Gastrostomy and Jejunostomy

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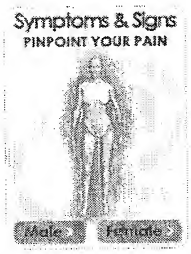

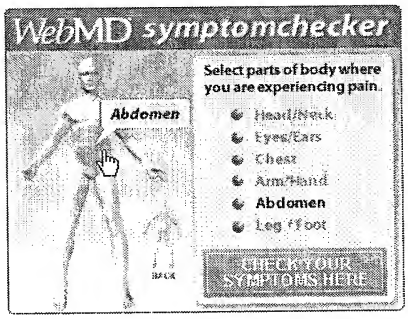

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APPENDIX A-1

enteral

A method of nutritient delivery where fluid is given directly into the gastrointestinal tract.

(16 Dec 1997)

Previous: entastic, entellus, Entemopoxvirus, enter, enteradenography, enteradenology
Next: enteralgia, enteral nutrition, enteramine, enterdynia, enterectasis

APPENDIX A-2

Digestive Diseases Dictionary E - K

E

previous page F G H I J K next page

Eagle-Barrett Syndrome
(EE-gul BAH-rut sin-drohm)

See Prune Belly Syndrome.

Electrocoagulation
(ee-LEK-troh-koh-ag-yoo-LAY-shun)

A procedure that uses an electrical current passed through an endoscope to stop bleeding in the digestive tract and to remove affected tissue.

Electrolytes
(ee-LEK-troh-lyts)

Chemicals such as salts and minerals needed for various functions in the body.

Encopresis
(en-koh-PREE-sis)

Accidental passage of a bowel movement. A common disorder in children.

Endoscope
(EN-doh-skohp)

A small, flexible tube with a light and a lens on the end. It is used to look into the esophagus, stomach, duodenum, colon, or rectum. It can also be used to take tissue from the body for testing or to take color photographs of the inside of the body. Colonoscopes and sigmoidoscopes are types of endoscopes.

Endoscopic Papillotomy
(en-doh-SKAW-pik pah-pih-LAW-tuh-mee)

APPENDIX A-3

See Endoscopic Sphincterotomy.

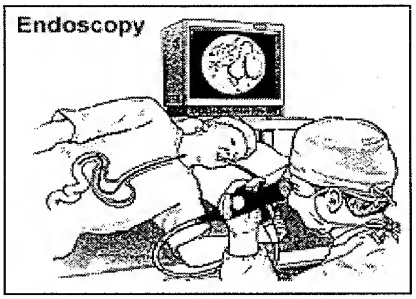
Endoscopic Retrograde Cholangiopancreatography (ERCP) *(en-doh-SKAW-pik REH-troh-grayd koh-LAN-jee-oh-PANG-kree-uh-**TAW**-gruh-fee)*

A test using an x-ray to look into the bile and pancreatic ducts. The doctor inserts an endoscope through the mouth into the duodenum and bile ducts. Dye is sent through the tube into the ducts. The dye makes the ducts show up on an x-ray.

Endoscopic Sphincterotomy
(en-doh-SKAW-pik sfeenk-tuh-RAW-tuh-mee)

An operation to cut the muscle between the common bile duct and the pancreatic duct. The operation uses a catheter and a wire to remove gallstones or other blockages. Also called endoscopic papillotomy.

Endoscopy
(en-DAW-skuh-pee)



A procedure that uses an endoscope to diagnose or treat a condition.

Enema
(EN-uh-muh)

A liquid put into the rectum to clear out the bowel or to administer drugs or food.

Enteral Nutrition
(EN-tuh-rul noo-TRISH-un)

A way to provide food through a tube placed in the nose, the stomach, or the small intestine. A tube in the nose is called a nasogastric or nasoenteral tube. A tube that goes through the skin into the stomach is called a gastrostomy or percutaneous endoscopic gastrostomy (PEG). A tube into the small intestine is called a jejunostomy or percutaneous endoscopic jejunostomy (PEJ) tube. Also called tube feeding. See also Gastrostomy and Jejunostomy.

Enteritis
(en-tuh-RY-tis)

An irritation of the small intestine.

Enterocele
(EN-tuh-roh-seel)

A hernia in the intestine. See also Hernia.

Enteroscopy
(en-tuh-RAW-skuh-pee)

An examination of the small intestine with an endoscope. The

1: JPEN J Parenter Enteral Nutr. 1992 Nov-Dec;16(6):499-504.

Links

Improved growth and disease activity after intermittent administration of a defined formula diet in children with Crohn's disease.

Polk DB, **Hattner JA**, **Kerner JA Jr**.

Department of Pediatrics, Stanford University School of Medicine, California.

Growth failure is the most common extraintestinal manifestation of Crohn's disease in childhood, occurring in up to 50% to 88% of affected patients. Previous studies have shown malnutrition to be the most likely cause of the decrease in height and weight velocities in these children. The purpose of this study was to determine the effect of an intermittent defined formula diet on growth and disease activity in children with Crohn's disease and growth failure. Six Tanner stage I-II patients, mean age 13.6 years with height less than the 5th percentile or height velocity less than the 3rd percentile were enrolled in a 1-year prospective study. An isotonic, hydrolyzed whey, medium-chain triglyceride formula was given by nocturnal nasogastric infusion at a caloric equivalent of 50th percentile for age, as the exclusive nutrient source 1 out of 4 months during a 1-year period. A 2-week exclusion diet and a 2-week low-residue diet followed the defined formula diet before resuming the regular diet for 2 months. Patients served as their individual control based on observations of at least 1 year before the study. Height and weight velocity significantly increased. Prednisone intake significantly decreased, and significant improvement was seen in disease activity, albumin, and somatomedin C. The results indicate that an intermittent defined formula diet can improve growth failure and significantly decrease disease activity in children with Crohn's disease.

PMID: 1494204 [PubMed - indexed for MEDLINE]

APPENDIX A-1

Note: Performing your original search, ***"defined formula diet"***, in PubMed will retrieve *39* citations.

1: Digestion. 1986;35(3):158-69.

Links

Effect of Ensure, a defined formula diet, in patients with Crohn's disease.

Imes S, Pinchbeck B, Dinwoodie A, Walker K, Thomson AB.

A prospective controlled 6-month study was undertaken to compare the effect of Ensure, a defined formula dietary supplement, and diet counselling in 122 outpatients with Crohn's disease. The compliance to Ensure was poor due to a high incidence of side effects. Taking any amount of Ensure reduced the need for surgery and the amount of hospitalization. There was a trend for patients receiving Ensure to experience a decline in the value of their Crohn's disease activity index (p less than 0.10). No consistent effects of Ensure were seen on the amount of work missed due to Crohn's disease, in laboratory measurements, in the need for prednisone or Salazopyrin. The vitamin B12 intake was improved, but otherwise nutrient intake declined due to a decreased food intake. Thus, certain beneficial clinical trends were associated with taking Ensure, but larger numbers of compliant patients will need to be studied to better assess the long-term role of defined formula diets in the management of outpatients with Crohn's disease.

PMID: 3536644 [PubMed - indexed for MEDLINE]

APPENDIX B-2

Alteration of the fiber and lipid components of a defined-formula diet: effects on stool characteristics, nutrient digestibility, mineral balance, and energy metabolism in humans[1–3]

Gregory D Sunvold, Evan C Titgemeyer, Leslie D Bourquin, George C Fahey Jr, and Keith A Garleb

ABSTRACT Eighteen healthy males with a body weight of 70.0 ± 3.1 kg consumed three defined-formula diets that varied only in their fiber and/or lipid components: *1*) 6.4% fiber (100% soy polysaccharides) and 13.1% lipid [50% medium-chain triacylglycerols (MCTs), 40% corn oil, and 10% soy oil]; 2) 3.4% fiber (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) and 15.6% lipid (20% MCTs, 50% canola oil, and 30% high oleic acid safflower oil); and *3*) 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1). Consumption of diet 2 resulted in slightly firmer stools and provided the greatest amount of fecal output per unit fiber intake. Total dietary fiber (TDF) digestibility was lowest for men fed diets 2 and 3, but nitrogen and lipid digestibilities and energy metabolism criteria were not different among diets. Although mineral excretion patterns differed among treatments, fiber and lipid components of the diets appeared not to be responsible for these differences. Results indicate that fecal output can be maintained with a lower intake of a blend of oat fiber, gum arabic, and carboxymethylcellulose compared with soy polysaccharides. Except for TDF digestibility, alteration of amounts and/or sources of fiber and lipid components of defined-formula diets used in this experiment did not alter nutrient digestibility, energy metabolism, or mineral retention. *Am J Clin Nutr* 1995;62:1252–60.

KEY WORDS Defined-formula diet, liquid, fiber, lipid, minerals, digestibility, feces, absorption, humans, metabolism

INTRODUCTION

Defined-formula diets have been fed for several decades (1–3), but inclusion of fiber in defined-formula diets is relatively recent. Slavin et al (4) fed defined-formula diets with and without soy polysaccharides and found that fecal weight was increased and intestinal transit time was decreased when subjects consumed diets containing fiber. The addition of a single source of fiber (ie, soy fiber) to defined-formula diets increased diet tolerance and, consequently, allowed increased dietary intake by burn patients (J Williamson, DM Heimbach, J Marvin, unpublished observations, 1985) and improved the stool consistency of head-injured patients (5).

Research with normal diets has suggested many benefits of dietary fiber inclusion (6–8). However, the effects of fiber on individuals are generally dependent on its source (7). Research by Bourquin et al (9) demonstrated that blends of oat fiber, gum arabic, and carboxymethylcellulose resulted in a moderate amount of in vitro fermentation by human fecal microflora and greater water-holding capacity (indicative of stool bulking) compared with soy polysaccharides. A similar blend of fibers added to a defined-formula diet fed to rats resulted in increased fecal weight with no effect on weight gain, intake, nitrogen balance, or retention of calcium and magnesium (10). Therefore, this blend of fibers was able to improve stool bulking and to provide a moderate amount of fermentation end products (short-chain fatty acids; SCFAs) thought responsible to maintain colonic function and structure (8) while not interfering with nutrient utilization.

The primary objective of the current experiment was to evaluate the use of a blend of fiber sources (oat fiber, gum arabic, and carboxymethylcellulose) in a defined-formula diet compared with a diet containing soy polysaccharides. In addition, a third diet was formulated to contain the same blend of fibers plus lipid sources that had a saturated, monounsaturated, and polyunsaturated fatty acid profile recommended by the American Heart Association (11).

SUBJECTS AND METHODS

Subjects

Eighteen male graduate students [age: 32.2 ± 2.0 y, body mass index (in kg/m^2): 23.1 ± 0.9, body weight: 70.0 ± 3.1 kg] from the University of Illinois at Urbana-Champaign volunteered to participate in this experiment. Four weeks before starting the experiment, subjects had physical examinations and all were found to be free of any digestive or metabolic

[1] From the Department of Animal Sciences and Division of Nutritional Sciences, University of Illinois, Urbana, IL, and Medical Nutrition Research and Development, Ross Products Division of Abbott Laboratories, Columbus, OH.

[2] Supported by Ross Products Division of Abbott Laboratories, Columbus, OH.

[3] Address reprint requests to GC Fahey Jr, Department of Animal Sciences, University of Illinois, 132 ASL, 1207 West Gregory Drive, Urbana, IL 61801.

Received January 19, 1995.
Accepted for publication August 14, 1995.

APPENDIX B-3

disorders. In addition, informed-consent forms approved by the University of Illinois Institutional Review Board were signed by each subject before participating in the experiment.

Diets

The three diets consumed by the subjects were similar in composition except for their fiber and lipid sources and were as follows: *1*) 6.4% fiber [100% soy polysaccharides (Fibrim; Protein Technologies International, St Louis) and 13.1% lipid [50% medium-chain triacylglycerols (MCTs), 40% corn oil, and 10% soy oil]; *2*) 3.4% fiber [75% oat fiber (Snowite; Canadian Harvest, Cambridge, MN), 17.5% gum arabic (Nutriloid arabic; TIC Gums Inc, Belcamp, MD), and 7.5% carboxymethylcellulose (Ticalose 15; TIC Gums, Inc)] and 15.6% lipid (20% MCTs, 50% canola oil, and 30% high oleic acid safflower oil); and *3*) 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1). Diets were formulated to contain ≈4.6% protein (sodium and calcium caseinates), 3.8% lipid, 14.2% carbohydrate (hydrolyzed cornstarch), 1.5% fiber, 0.7% vitamins and minerals, other metabolites, and 75.2% water. The chemical composition of the diets is reported in **Tables 1** and **2.**

Experimental methods

The experiment was divided into three time periods. In each period subjects consumed a normal self-selected diet for 5 or 6 d followed by consumption of a treatment diet for 12 d. Each subject consumed a different diet each period. When consuming a treatment diet, the subjects were instructed to consume only the diet and deionized water obtained from a water purification system (Millipore Corporation, Marlboro, MA) fitted with a 0.22-μm pore size filter. Subjects also were allowed to chew sugarless gum.

Diets were mixed daily with 1 g artificial sweetener (Nutra-Sweet; The NutraSweet Company, Deerfield, IL) and 2–6 g artificial flavors (Vari Flavors flavor packets; Ross Products Division of Abbott Laboratories, Columbus, OH) per 457 g enteral diet. Subjects were fed at a meal site on campus during the following time periods: breakfast, 0700–0800; lunch, 1130–1315; and dinner, 1700–1800. The resting energy expenditure of each subject was determined by the Harris-Benedict equation: 66.47 + [13.75 × weight (in kg)] + [5.0 × height (in cm)] − [6.75 × age (in y)]. The resulting value then was multiplied by an activity factor to determine the amount of energy fed to each subject (12). For period one, an activity factor of 1.4 was used for each individual. Subjects were weighed daily during consumption of treatment diets. Because a minor amount of weight loss ($\bar{x}$ = 0.80 kg) occurred during the first period in some subjects, the average activity factor used was 1.42 for periods two and three. Subjects consumed ≈26%, 34%, and 40% of their total daily intake at breakfast, lunch, and dinner, respectively.

Subjects fasted overnight and serum samples were collected before (1 d before consumption of a treatment diet) and after (1 d after consumption of a treatment diet) each period. Subjects collected all urine and feces during the last 8 d of each 12-d period. All diets were sampled on days 4–11 of the 12-d period. However, only diet, urine, and fecal samples corresponding to the last 5 d of treatment diet consumption were saved for future analyses.

Urine and fecal samples were received from subjects three times daily. Subjects were given 500-mL bottles containing 10 mL 2 mol HCl/L for urine collection. Collected urine was weighed and refrigerated (4 °C) until it was composited. Daily urine samples from the last 5 d of collection were composited proportionally based on the amount of daily urine excretion. An aliquot of ≈120 mL urine was combined with 1 mL 6 mol HCl/L and stored for future analyses (−20 °C).

Feces were weighed and their consistency was scored. Feces were frozen (−20 °C) until lyophilized (FTS Systems, Stone Ridge, NY). When diet and fecal samples were dry, they were allowed to equilibrate in air and were then weighed and ground with a food processor (West Bend, West Bend, WI). Samples were allowed to equilibrate in air again and then composited. Diet and fecal samples corresponding to the last 5 d of collection in each period were composited. Similar daily quantities (50 g) of diet samples were composited whereas daily fecal samples were proportionally composited based on the amount of fecal dry matter excreted daily.

TABLE 1
Chemical composition of defined-formula diets[1]

	Diet 1	Diet 2	Diet 3
DM (%)	22.8	22.4	22.8
Organic matter (% of DM)	96.4	96.1	96.5
Crude protein (% of DM)	17.3	17.8	17.8
Lipid (% of DM)	13.1	15.6	14.5
TDF (% of DM)	6.4	3.4	4.4
GE (kJ/g DM)	20.9	21.3	20.9

[1] DM, dry matter of liquid diet; TDF, total dietary fiber; GE, gross energy. All diets contained supplemental vitamin A, vitamin D, vitamin E, vitamin K, vitamin C, folic acid, thiamin, riboflavin, vitamin B-6, vitamin B-12, niacin, choline, biotin, pantothenic acid, sodium, potassium, chloride, calcium, phosphorus, magnesium, iodine, manganese, copper, zinc, iron, selenium, chromium, molybdenum, taurine, and carnitine. Diet 1: 6.4% fiber (100% soy polysaccharides) and 13.1% lipid (50% medium-chain triacylglycerols, 40% corn oil, 10% soy oil); diet 2: 3.4% fiber (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) and 15.0% lipid (20% medium-chain triacylglycerols, 50% canola oil, and 30% high oleic acid safflower oil); diet 3: 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1).

TABLE 2
Mineral composition of defined-formula diets[1]

	Diet 1	Diet 2	Diet 3
		mg/kg	
Calcium	5568	5118	3914
Phosphorus	3923	5223	3164
Potassium	7817	8716	8478
Magnesium	2359	2489	2391
Zinc	101	109	96
Iron	75	77	60
Copper	10	10	11

[1] Values expressed on the basis of dry matter. Diet 1: 6.4% fiber (100% soy polysaccharides) and 13.1% lipid (50% medium-chain triacylglycerols, 40% corn oil, and 10% soy oil); diet 2: 3.4% fiber (75% oat fiber, 17.5% gum arabic and 7.5% carboxymethylcellulose) and 15.6% lipid (20% medium-chain triacylglycerols, 50% canola oil, and 30% high oleic acid safflower oil); diet 3: 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1).

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Analytical techniques

Dry matter, organic matter, and the Kjeldahl nitrogen content of diets and feces were determined by using methods of the Association of Official Analytical Chemists (AOAC) (13). Total dietary fiber (TDF) in diets and feces was determined by the method of Prosky et al (14). The total lipid content of diets and feces was determined by using the method of the American Association of Cereal Chemists (AACC) (15). Diet and fecal sample preparations for mineral analyses were conducted according to an AOAC method (13). Urine samples were prepared for mineral analyses by centrifugation at 20 000 × *g* for 20 min at 4 °C and removal of the supernate. Mineral concentrations (calcium, potassium, magnesium, zinc, iron, and copper) in diets, urine, and feces were determined by using an atomic absorption spectrophotometer (model 306; Perkin-Elmer, Norwalk, CT). The phosphorus content of diets, feces, and urine was determined by an AOAC method (13). Bomb calorimetry (model 1261; Parr Instrument Company, Moline, IL) was used to determine the gross energy (GE) content of diets, urine, and feces, and these values were used to calculate the digestible energy (DE) and metabolizable energy (ME) contents of the diets. Urine samples were prepared for energy determination by adding 1 mL urine to 1 g α-cellulose and drying at 55 °C for 4 h. One-gram samples were combusted, and GE values of samples were corrected for addition of α-cellulose. The concentration of creatinine in the daily collection of urine from each subject was determined with a diagnostic kit (no. 555; Sigma Chemical Co, St Louis). The daily urinary creatinine concentration was multiplied by daily urine output to calculate total daily creatinine excretion.

Serum samples were prepared from 5 mL blood collected into nonheparinized tubes. The blood was allowed to clot for 30–60 min and then centrifuged at 1300 × *g* for 10 min at 23 °C with a Fisher Centrific centrifuge (model 0151; Becton Dickinson, Parsippany, NJ). The serum was transferred to another tube and refrigerated (4 °C) until analyzed. Boehringer Mannheim (Indianapolis) method nos. 816356, 489604, 857428, 857427, 857429, 977145, 816302, 857426, 620174, 820637, 836246, 820639, 816354, 851125, 851126, 816355, 763147, and 882763 were used to prepare creatinine, blood urea nitrogen, calcium, phosphorus, glucose, total bilirubin, cholesterol, total protein, albumin, sodium, potassium, chloride, alkaline phosphatase, alanine aminotransferase-glutamic pyruvic transaminase, aspartate amino transferase/serum glutamic pyruvic transaminase, γ-glutamyl transferase, creatine phosphokinase, and amylase, respectively, for analysis. Sigma's kit no. 50 was used to prepare sorbitol dehydrogenase for analysis. Serum metabolites then were colorimetrically determined by using an auto analyzer (Hitachi 704; Boehringer Mannheim).

Statistics

This experiment was analyzed as a Latin-square design. Subject and period were the blocking factors. The model statement used by the General Linear Models procedure of SAS included diet, subject, and period (16). Least-squares means are reported along with the SEMs for all treatments. Means were separated by the least-significant-difference procedure protected by a significant ($P < 0.05$) F test (17).

RESULTS

Total creatinine output by subjects was used as an indication of completeness of urine collection. Daily urinary creatinine excretion (data not shown) by one subject in periods two and three was less than half that of the other subjects. In addition, the same subject submitted no fecal sample in period three. Thus, results from this subject for periods two and three were eliminated from statistical analyses. Because urinary creatinine values in period one of this subject were similar to those of other subjects of similar body weight, data from period one for this subject were included in the statistical analysis of the data. Another subject did not comply with proper diet consumption during period two. Thus, results from this subject during period two were eliminated from statistical analyses. Daily creatinine output values gave no indication that urine collection was incomplete by any other subjects. With regard to serum chemistries, some differences due to diet did occur; however, no values were outside the normal range (data not shown). Slight variations in diet formulation caused the TDF and lipid concentration among diets to vary up to three percentage units.

TABLE 3
Nutrient intake and digestibility by healthy men fed defined-formula diets[1]

	Diet 1	Diet 2	Diet 3	SEM	P^2
DM intake (g/d)	494.9[a]	481.3[b]	496.1[a]	1.7	<0.01
OM intake (g/d)	476.9[a]	462.5[b]	478.6[a]	1.6	<0.01
Nitrogen intake (g/d)	13.7[a]	13.7[a]	14.1[b]	0.0	<0.01
Lipid intake (g/d)	64.7[a]	75.0[b]	71.9[c]	0.3	<0.01
TDF intake (g/d)	31.7[a]	16.5[b]	22.5[c]	0.2	<0.01
DM digestibility (%)	95.1[a]	94.0[b]	93.9[b]	0.2	<0.01
OM digestibility (%)	96.3[a]	95.1[b]	94.7[b]	0.2	<0.01
Nitrogen digestibility (%)	91.6	92.7	92.4	0.4	0.19
Lipid digestibility (%)	97.1	97.1	97.3	0.1	0.38
TDF digestibility (%)	80.1[a]	21.6[b]	30.8[b]	3.4	<0.01

[1] DM, dry matter of liquid diet; OM, organic matter; TDF, total dietary fiber. Diet 1: 6.4% fiber (100% soy polysaccharides) and 13.1% lipid (50% medium-chain triacylglycerols, 40% corn oil, and 10% soy oil); diet 2: 3.4% fiber (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) and 15.6% lipid (20% medium-chain triacylglycerols, 50% canola oil, and 30% high oleic acid safflower oil); diet 3: 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1). Means in the same row with different superscript letters are significantly different, $P < 0.05$.

[2] The overall treatment effect.

Intakes of dry matter, organic matter, and TDF were lowest ($P < 0.05$) when men consumed diet 2 (**Table 3**). Nitrogen intake was greatest when men consumed diet 3 ($P < 0.05$) whereas lipid intake was greatest when men consumed diet 2 ($P < 0.05$) and least when men consumed diet 1 ($P < 0.05$). Dietary dry matter and organic matter digestibilities were greatest when men consumed diet 1 ($P < 0.05$). Nitrogen and lipid digestibilities were not different among diets ($P > 0.05$). Digestibility of TDF was greater when men consumed diet 1 (which contained soy polysaccharides) compared with the fiber-blend diets ($P < 0.05$).

The number of defecations per day was not different ($P > 0.05$) when men consumed different diets (**Table 4**). Stool consistency was slightly firmer when diet 2 was consumed ($P < 0.05$). Wet fecal output was not different among diets ($P > 0.05$). Fecal dry matter output was greater when men consumed the fiber-blend diets (diets 2 and 3) compared with the soy polysaccharide diet (diet 1) ($P < 0.05$). Fecal dry matter percentage and wet and dry stool outputs per gram of TDF intake also were least when men consumed diet 1 ($P < 0.05$) and greatest when men consumed diet 2 ($P < 0.05$).

Intake of GE was greatest ($P < 0.05$) when men consumed diet 3 (**Table 5**). DE and ME were not different among diets when expressed as kJ/d ($P > 0.05$). When DE and ME were expressed as kJ/g dry matter intake, diet 2 resulted in the highest ($P < 0.05$) value. When DE and ME were expressed as a percentage of GE, diet 1 resulted in the highest value ($P < 0.05$). ME, expressed as a percentage of DE, was not different among diets ($P > 0.05$).

Intake and fecal excretion of calcium were lowest ($P < 0.05$) when men consumed diet 3 (**Table 6**). Calcium intake, absorption, and retention (mg/d) were greatest when diet 1 was consumed ($P < 0.05$). Phosphorus intake, urinary and fecal excretion, absorption, and retention were greatest when men consumed diet 2 ($P < 0.05$). Phosphorus intake, absorption, and retention were lowest when men consumed diet 3 ($P < 0.05$). Retention of both calcium and phosphorus, expressed as a percentage of intake, was not different among treatments.

Potassium intake, absorption, and retention were lowest when men consumed diet 1 ($P < 0.05$). Magnesium intake, fecal excretion, and total excretion generally were lowest ($P < 0.05$) whereas absorption and retention generally were greatest ($P < 0.05$) when men consumed diet 1. Zinc intake and urinary, fecal, and total zinc excretion were greatest when men consumed diet 2 ($P < 0.05$). No differences among treatments were noted for zinc absorption or retention. Iron intake, fecal excretion, absorption, and retention (mg/d) were lowest when men consumed diet 3 ($P < 0.05$). Retention, expressed as a percentage of intake, was not different among treatments. Copper intake was greatest when men consumed diet 3 ($P < 0.05$). Fecal excretion and total excretion of copper were generally greatest ($P < 0.05$) whereas absorption and retention of copper were lowest ($P < 0.05$) when men consumed diet 2.

DISCUSSION

Fiber has been used to improve stool output and consistency when defined-formula diets are consumed (4). However, research with dogs and cats indicates that not all sources of fiber improve stool consistency (18, 19), so combining sources could be useful in optimizing this characteristic. Use of a blend of fibers in a defined-formula diet has not been investigated previously.

The oat fiber–gum arabic–carboxymethylcellulose blend (diets 2 and 3) used in the current experiment was chosen based on results of previous in vitro fermentation and in vivo metabolism studies. In vitro fermentation techniques have been successfully used to predict digestion and fermentative properties of fiber in cats (18) and dogs (19) and also may be used to predict its water-holding capacity (20, 21). This latter criterion provides some indication of the ability of fiber to provide stool bulk. In an attempt to develop a blend of fibers with moderate fermentative properties and optimal water-holding-capacity characteristics, several blends of oat fiber, gum arabic, and carboxymethylcellulose were evaluated by Bourquin et al (9). Oat fiber and carboxymethylcellulose result in little fermentation whereas gum arabic is extensively fermented (10, 21). The carboxymethylcellulose resulted in more than twice the water-holding capacity of oat fiber and gum arabic (9). These results indicated that a modest amount of SCFA production, water-holding capacity, and substrate disappearance occurred when a blend of fibers consisting of 75% oat fiber, 20% gum arabic, and 5% carboxymethylcellulose were fermented in vitro using

TABLE 4
Fecal characteristics of healthy men fed defined-formula diets[1]

	Diet 1	Diet 2	Diet 3	SEM	P^2
Number of defecations/d	1.0	1.0	1.0	0.1	0.79
Fecal consistency[3]	3.2[a]	3.0[b]	3.3[a]	0.1	0.03
Wet fecal output (g/d)	150.6	121.6	136.7	8.5	0.07
Fecal dry matter output (g/d)	24.1[a]	29.1[b]	30.5[b]	1.2	<0.01
Fecal dry matter (%)	17.2[a]	24.5[b]	22.5[c]	0.5	<0.01
Wet fecal output (g/g TDF intake)	4.7[a]	7.4[b]	6.0[c]	0.3	<0.01
Dry fecal output (g/g TDF intake)	0.8[a]	1.8[b]	1.4[c]	0.1	<0.01

[1] TDF, total dietary fiber. Diet 1: 6.4% fiber (100% soy polysaccharides) and 13.1% lipid (50% medium-chain triacylglycerols, 40% corn oil, and 10% soy oil); diet 2: 3.4% fiber (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) and 13.0% lipid (20% medium-chain triacylglycerols, 50% canola oil, and 30% high oleic acid safflower oil); diet 3: 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1). Means in the same row with different superscript letters are significantly different, $P < 0.05$.

[2] The overall treatment effect.

[3] 1 = hard, dry, pellets; small, hard mass; 2 = hard, formed, dry stool; remains firm and soft; 3 = soft, formed, moist, softer stool that retains shape; 4 = soft, unformed stool that assumes shape of container, pudding-like; 5 = watery, liquid that can be poured.

TABLE 5
Digestible (DE) and metabolizable energy (ME) values for healthy men fed defined-formula diets[1]

	Diet 1	Diet 2	Diet 3	SEM	P^2
GE intake (kJ/d)	10 334.4[a]	9837.2[a]	10 444.1[b]	36.04	0.02
DE					
(kJ/d)	9930.0	9815.8	9912.4	45.92	0.18
(kJ/g DM intake)	20.1[a]	20.5[b]	20.1[a]	0.04	<0.01
(% of GE)	96.1[a]	95.4[b]	94.9[b]	0.19	<0.01
ME					
(kJ/d)	9622.8	9513.9	9588.5	53.04	0.34
(kJ/g DM intake)	19.3[a]	19.7[b]	19.3[a]	0.04	<0.01
(% of GE)	93.1[a]	92.4[ab]	91.8[b]	0.29	0.01
(% of DE)	96.9	96.9	96.7	0.22	0.73

[1] GE, gross energy; DM, dry matter of liquid diet. Diet 1: 6.4% fiber (100% soy polysaccharides) and 13.1% lipid (50% medium-chain triacylglycerol, 40% corn oil, and 10% soy oil); diet 2: 3.4% fiber (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) and 15.6% lipid (20% medium-chain triacylglycerols, 50% canola oil, and 30% high oleic acid safflower oil); diet 3: 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1). Means in the same row with different superscript letters are significantly different, $P < 0.05$.

[2] The overall treatment effect.

human feces as the inoculum source (9). A similar blend of fibers (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) was incorporated into a defined-formula diet and fed to rats (10). Results indicated that fecal weight could be increased when diets containing the blend of fibers were fed compared with a diet containing soy polysaccharides. The fiber blend did not affect weight gain, food intake, efficiency of weight gain, nitrogen balance, or mineral retention. Thus, the fiber blend produced desirable characteristics using in vitro and in vivo models. The current experiment was designed to evaluate the efficacy of including a blend of these fibers in a defined-formula diet for humans.

The chemical composition of each source of fiber used in this experiment consisted of ≈80% or more TDF. Soy polysaccharides are primarily insoluble fiber and consist of ≈10% crude protein, 26% galactose, 16% uronic acids, 16% glucose, 15% arabinose, and minor amounts of rhamnose, xylose, and mannose (21). Oat fiber is insoluble in aqueous solutions and consists of ≈50% glucose, 43% xylose, and minor amounts of crude protein, arabinose, galactose, and uronic acids (21). Gum arabic is soluble in aqueous solutions and consists of ≈35% galactose, 28% arabinose, 14% uronic acids, 12% rhamnose, and minor amounts of crude protein (21). Carboxymethylcellulose is a synthetic fiber source that is a cellulose polymer with carboxymethyl group side chains and is soluble in aqueous solutions.

Intakes of dry matter and organic matter were slightly less when men consumed diet 2 because of the slightly lower amount of dry matter in diet 2 than in diets 1 and 3. Differences in dietary lipid concentration resulted in differences in lipid intake among diets. Although intakes of nitrogen and lipid were different among diets, there were no differences in nitrogen and lipid digestibility. In addition, digestibilities were relatively high (> 90%) for all diets. The amount of fecal nitrogen excreted by humans consuming a diet similar to diet 1 was comparable with fecal nitrogen excretion in the current experiment (22). Other diets with a composition similar to diets in the current experiment had similar lipid and nitrogen digestibilities (23). Intake of TDF was reflective of the TDF concentration of the diets. Fiber digestibility was much lower by men consuming the fiber blend (diets 2 and 3) compared with men consuming soy polysaccharides (diet 1). This was responsible for the slightly greater digestibilities of dry matter and organic matter by men consuming diet 1.

As previously mentioned, in vitro results were used to formulate the blend of fibers in this experiment. Extrapolation of in vitro results indicates that a blend similar to the one fed in the current experiment would result in the disappearance of ≈20% TDF (10). This corresponds reasonably well with the 21.6% and 30.8% TDF digestibilities of diets containing this blend of fibers. However, a somewhat greater fiber digestion from diet 1 occurred in vivo (TDF digestibility of 80.1%) compared with the in vitro digestion of soy polysaccharides (substrate disappearance of 60.3%; 10). This difference may be due to a retention time in vivo that was longer than that in vitro (24 h). Evidence exists for a longer (ie, 54 h) intestinal transit time by humans consuming a diet similar to the one containing soy polysaccharides (24). This is supported by the fact that soy polysaccharides fermented for 48 h by human fecal microflora resulted in ≈75% substrate disappearance (21).

The major end products of colonic fiber fermentation are SCFAs. The proportions of the major SCFAs produced during fermentation (acetate, propionate, butyrate) vary for different fiber sources (9, 18–21). An experiment with rats fed diets similar to those used in the current experiment resulted in different concentrations of specific SCFAs in the cecum, depending on the type and amount of fiber in the diet (10). Thus, the potential exists to alter the profile of fermentation end products in the colon by selecting certain substrates. Other research has suggested that certain SCFAs may be important energy substrates for intestinal cells (25). Therefore, SCFAs may be important for maintaining intestinal health, and their concentration in the colon can be altered by changing the source of dietary fiber.

Maintaining fecal consistency is an important reason for adding fiber to defined-formula diets. Although diet 2 resulted in a slightly lower fecal consistency score than did the other diets, all diets resulted in acceptable fecal consistency. Using similar criteria to score fecal samples, Slavin et al (4) reported a lower fecal consistency score (≈2.3) for humans consuming defined-formula diets similar to those fed in the current experiment. This lower value may reflect the lower wet fecal output

TABLE 6
Intake, excretion, absorption, and retention of minerals by healthy men consuming defined-formula diets[1]

	Diet 1	Diet 2	Diet 3	SEM	P^2
Calcium					
Intake (mg/d)	2751.8[a]	2464.1[b]	1943.8[c]	12.5	<0.01
Excretion (mg/d)					
Urinary	189.6	166.6	206.1	20.9	0.40
Fecal	1771.4[a]	1759.8[a]	1203.2[b]	61.7	<0.01
Total	1961.0[a]	1926.5[a]	1409.3[b]	66.6	<0.01
Absorbed					
(mg/d)	980.4[a]	704.3[b]	740.6[b]	66.6	0.01
(% of intake)	35.0[ab]	28.8[a]	38.3[b]	2.4	0.03
Retained					
(mg/d)	790.7[a]	537.6[b]	534.5[b]	71.6	0.03
(% of intake)	28.1	22.0	27.7	2.7	0.21
Phosphorus					
Intake (mg/d)	1941.5[a]	2512.5[b]	1570.8[c]	13.4	<0.01
Excretion (mg/d)					
Urinary	528.3[a]	957.3[b]	515.7[a]	14.9	<0.01
Fecal	895.3[a]	925.6[b]	668.8[a]	30.2	<0.01
Total	1423.6[a]	1883.0[b]	1184.5[c]	35.6	<0.01
Absorbed					
(mg/d)	1046.2[a]	1586.8[b]	902.0[c]	32.9	<0.01
(% of intake)	53.5[a]	63.2[b]	57.4[a]	1.4	<0.01
Retained					
(mg/d)	517.9[a]	629.5[b]	386.3[c]	36.3	<0.01
(% of intake)	26.4	25.1	24.7	1.8	0.77
Potassium					
Intake (mg/d)	3870.8[a]	4193.6[b]	4205.1[b]	15.0	<0.01
Excretion (mg/d)					
Urinary	2533.2	2702.2	2724.3	72.5	0.15
Fecal	520.3	383.3	401.6	48.3	0.11
Total	3053.6	3085.5	3125.9	54.8	0.65
Absorbed					
(mg/d)	3350.5[a]	3810.3[b]	3803.5[b]	54.7	<0.01
(% of intake)	86.5[a]	90.8[b]	90.4[b]	1.2	0.03
Retained					
(mg/d)	817.2[a]	1108.1[b]	1079.3[b]	60.8	<0.01
(% of intake)	21.1[a]	26.4[b]	25.5[b]	1.5	0.04
Magnesium					
Intake (mg/d)	1167.6[a]	1197.7[b]	1186.1[b]	4.2	<0.01
Excretion (mg/d)					
Urinary	236.5	239.1	228.1	7.0	0.50
Fecal	776.9[a]	927.3[b]	863.9[ab]	31.2	<0.01
Total	1013.4[a]	1166.5[b]	1092.0[ab]	33.1	0.01
Absorbed					
(mg/d)	390.7[a]	270.4[b]	322.3[ab]	32.3	0.04
(% of intake)	33.1[a]	22.8[b]	27.4[ab]	2.6	0.03
Retained					
(mg/d)	154.2[a]	31.3[b]	94.2[ab]	34.1	0.05
(% of intake)	12.8[a]	2.8[b]	8.1[ab]	2.8	<0.05
Zinc					
Intake (mg/d)	50.0[a]	52.5[b]	47.6[c]	0.2	<0.01
Excretion (mg/d)					
Urinary	0.38[a]	0.45[b]	0.40[c]	0.01	<0.01
Fecal	39.3[a]	44.5[b]	38.0[a]	1.5	<0.01
Total	39.7[a]	45.0[b]	38.4[a]	1.5	<0.01
Absorbed					
(mg/d)	10.7	7.9	9.7	1.5	0.43
(% of intake)	20.5	15.0	20.0	2.8	0.31
Retained					
(mg/d)	10.3	7.5	9.3	1.5	0.42
(% of intake)	20.0	14.6	19.5	2.8	0.32

TABLE 6 *continued*
Intake, excretion, absorption, and retention of minerals by healthy men consuming defined-formula diets[1]

	Diet 1	Diet 2	Diet 3	SEM	P^2
Iron					
Intake (mg/d)	37.1[a]	37.1[a]	29.8[b]	0.2	<0.01
Excretion (mg/d)					
Urinary	0.1	0.2	0.5	0.3	0.51
Fecal	22.3[a]	22.6[a]	19.2[b]	1.1	0.05
Total	22.5	22.7	19.7	1.1	0.12
Absorbed					
(mg/d)	14.8[a]	14.5[a]	10.6[b]	1.1	0.02
(% of intake)	39.4	39.4	35.4	3.0	0.56
Retained					
(mg/d)	14.6[a]	14.4[a]	10.1[b]	1.2	0.02
(% of intake)	38.8	39.1	33.7	3.3	0.41
Copper					
Intake (mg/d)	5.0[a]	5.0[a]	5.3[b]	0.02	<0.01
Excretion (mg/d)					
Urinary	0.13	0.15	0.13	0.01	0.32
Fecal	3.3[a]	3.7[b]	3.4[ab]	0.1	0.04
Total	3.4[a]	3.9[b]	3.6[ab]	0.1	0.04
Absorbed					
(mg/d)	1.7[a]	1.3[b]	1.8[a]	0.1	<0.01
(% of intake)	33.0[a]	25.4[b]	35.1[a]	2.3	0.01
Retained					
(mg/d)	1.5[a]	1.1[b]	1.7[a]	0.1	<0.01
(% of intake)	30.4[a]	22.5[b]	32.5[a]	2.4	0.01

[1] Diet 1: 6.4% fiber (100% soy polysaccharides) and 13.1% lipid (50% medium-chain triacylglycerols, 40% corn oil, and 10% soy oil); diet 2: 3.4% fiber (75% oat fiber, 17.5% gum arabic, and 7.5% carboxymethylcellulose) and 15.6% lipid (20% medium-chain triacylglycerol, 50% canola oil, and 30% high oleic acid safflower oil); diet 3: 4.4% fiber (same as diet 2) and 14.5% lipid (same as diet 1). Means in the same row with different superscript letters are significantly different, $P < 0.05$.
[2] The overall treatment effect.

in a previous experiment (4) or may have been due to a slightly different interpretation of the stool consistency criteria used to assess this characteristic. The number of stools excreted per day was similar to other reported values (4).

Wet fecal output was numerically, but not statistically, decreased when men consumed fiber-blend diets. This was probably due to lower fiber intake when fiber-blend diets were consumed. However, when results were expressed as grams of wet fecal output per gram TDF intake, wet fecal output was greater with fiber-blend diets than with the soy polysaccharide diet. The diets did not contain the same concentration of TDF. To adjust for this, fecal output was not only expressed as g/d but also as g/g TDF intake (Table 4). Therefore, TDF intake varied among treatment groups; grams wet fecal output per gram TDF intake is a better indicator of fecal output than is total daily wet fecal output. Wet fecal output by men fed diet 1 was greater than wet fecal output for those consuming a similar amount of fiber per day in a similar defined-formula diet (4). This difference was probably due to a greater consumption of fiber in the current experiment.

The greatest fecal dry matter output occurred when men consumed diets containing the fiber blend. In addition, grams of dry fecal output per gram TDF intake increased when men consumed fiber-blend diets compared with the soy polysaccharide diet. These results reflect the lower fiber digestion from fiber-blend diets.

Although significant differences in GE intake occurred among treatment groups, differences in intake were small (9837–10444 kJ/d). Similarly, when DE and ME were expressed as kJ/g dry matter intake or as a percentage of GE, significant differences among diets occurred, but the range of values among diets was less than two percentage units. All diets resulted in relatively high DE (> 94% of GE) and ME (> 96% of DE) values.

Other research indicated that addition of fiber to a diet decreases energy digestibility in the small intestine (26) and slightly decreases energy digestibility in the entire gastrointestinal tract (27). Slightly lower energy digestion probably reflects the lower energy availability from fiber than from other dietary ingredients. Using diets similar to those fed in the current experiment, Heymsfield et al (23) found comparable energy digestibility values. Because energy digestibility values were ≈23 percentage units less in the small intestine (26) compared with those in the entire gastrointestinal tract in the present study, a considerable amount of energy digestion and absorption may occur in the large intestine of humans.

Differences in excretion, absorption, and retention of calcium, phosphorus, potassium, and iron were related to mineral intakes. For example, phosphorus intake was greatest by men consuming diet 2, and this diet also resulted in the greatest retention (mg/d) of phosphorus. A comparison of results from our experiment with results from other experiments also indicates that mineral intake influences mineral absorption. For example, more than a twofold greater absorption of calcium occurred in the current experiment with diet 1 compared with a similar diet in an experiment reported by Heymsfield et al (23). This increase probably occurred because nearly twice the

amount of calcium was consumed by men in the current experiment. A comparison of the phosphorus, potassium, and magnesium absorption values when men consumed the soy polysaccharide diet with values reported by Heymsfield et al (23) yielded a conclusion similar to that for calcium. Addition of soy polysaccharides to a defined-formula diet in an amount slightly greater than that fed in the present study resulted in no deleterious effect on the small intestinal absorption of zinc, iron, and copper or of calcium, phosphorus, or magnesium (28).

A mineral whose excretion and retention did not correspond with the amount ingested was copper. It does not appear that the type of fiber in the diet caused the lowered retention because diet 3 resulted in a retention similar to that of diet 1. However, high zinc intakes may decrease copper retention (29, 30). The greatest zinc intake occurred when men consumed diet 2; perhaps the higher zinc intake decreased the retention of copper when diet 2 was consumed. Another mineral whose excretion did not correspond with intake was magnesium. When men consumed diet 2, the lowest magnesium absorption occurred. These subjects also consumed a large amount of calcium and phosphorus compared with those fed other diets. Research with rats suggests that calcium and phosphorus may complex with magnesium and decrease its absorption (31). Perhaps the calcium and phosphorus intakes of men consuming diet 2 were high enough to cause magnesium to complex with calcium and phosphorus. Nonetheless, the amount of copper and magnesium absorbed was probably adequate because their intake was higher than recommended amounts (32).

Current reference daily intakes (RDI; 32) for calcium, phosphorus, magnesium, zinc, iron, and copper are 1200, 1200, 400, 15, 15, and 2.5 mg, respectively, for adults and children aged $\geq$ 4 y. All three diets resulted in intakes of these minerals that exceeded the current RDI. In addition, the daily reference value (DRV) for potassium intake is 3500 mg per 8372 kJ. All diets supplied potassium in excess of the DRV. These diets were formulated for elderly, inactive adults; therefore, mineral intakes in this experiment were considerably greater than those that would result from a substantially reduced total diet intake.

In summary, varying concentrations of each mineral in each diet resulted in intake differences among diets for all minerals evaluated. Resulting differences in mineral excretion among diets often were due to differences in intake and did not appear to be dependent on the type of fiber or lipid in the diet. In addition, Wang et al (10) found few differences in the absorption of calcium, magnesium, iron, and zinc between rats consuming a diet similar to the soy polysaccharide diet compared with a diet similar to the fiber-blend diets.

In conclusion, defined-formula diets containing soy polysaccharides or a blend of oat fiber, gum arabic, and carboxymethylcellulose resulted in extremely high (> 90%) nutrient (ie, protein, lipid) digestibility and energy metabolism without compromising mineral utilization. Addition of the fiber blend used in this experiment to a defined-formula diet can maintain fecal output with less added fiber compared with soy polysaccharides. Decreased amounts of fiber in a defined-formula diet may aid in diet delivery to the patient via nasogastric or gastric tubes. Lipid composition of the defined-formula diet had little effect on nutrient digestibility or metabolism.

Results from this experiment are only applicable to the certain types and amounts of fiber and lipids used in these diets. Further research with defined-formula diets should investigate the use of other blends of fiber to provide desirable fecal characteristics and maintain nutrient digestibility. In addition, further evaluation of the potential role of more fermentable substrates (eg, oligosaccharides) in providing SCFAs to maintain gut health is warranted. Development of defined-formula diets should continue to emphasize the long-term impact of these diets on health, in particular gut maintenance.

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